

Proposed Rule
LSA Document #12-414

DIGEST

Adds [856 IAC 7](#) to establish standards applicable to any prescription drug take back program, entities that may participate in prescription drug take back programs, and guidelines and standards for prescription drug take back programs. Effective 30 days after filing with the Publisher.

[IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses](#)

[856 IAC 7](#)

SECTION 1. [856 IAC 7](#) IS ADDED TO READ AS FOLLOWS:

ARTICLE 7. PRESCRIPTION DRUG TAKE BACK PROGRAMS

Rule 1. Purpose and Scope

[856 IAC 7-1-1](#) Purpose and scope

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 1. (a) This article establishes standards applicable to any:

- (1) prescription drug take back program;
- (2) entities that may participate in prescription drug take back programs; and
- (3) guidelines and standards for prescription drug take back programs.

(b) This article and these regulations are not intended to prohibit or otherwise curtail activities taking place through existing take back programs or events being run by statutorily authorized law enforcement agencies or municipal (or state and federal) solid waste programs.

(Indiana Board of Pharmacy; [856 IAC 7-1-1](#))

Rule 2. Definitions

[856 IAC 7-2-1](#) Definitions

Authority: [IC 25-26-23-2](#)

Affected: [IC 16-42-19](#); [IC 16-42-20](#); [IC 25-26-13-2](#); [IC 25-26-23](#)

Sec. 1. The definitions in [IC 25-26-13-2](#), [IC 16-42-19](#), [IC 16-42-20](#), and this rule apply throughout this article.

(Indiana Board of Pharmacy; [856 IAC 7-2-1](#))

[856 IAC 7-2-2](#) "Board" defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-13-3](#)

Sec. 2. "Board" means the Indiana board of pharmacy established under [IC 25-26-13-3](#).

(Indiana Board of Pharmacy; [856 IAC 7-2-2](#))

[856 IAC 7-2-3](#) "Drug return receptacle" defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-13-3](#)

Sec. 3. "Drug return receptacle" means the receptacle into which the consumer places the returned prescription drugs, whether or not it is the drug storage device.

(Indiana Board of Pharmacy; [856 IAC 7-2-3](#))

[856 IAC 7-2-4](#) "Drug storage device" defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-13-3](#)

Sec. 4. "Drug storage device" means the device in which the returned prescription drugs are stored after return by the consumer and before disposal.

(Indiana Board of Pharmacy; [856 IAC 7-2-4](#))

[856 IAC 7-2-5](#) "Entities" defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 16-28](#); [IC 25-26](#)

Sec. 5. "Entities" means those licensed facilities that are eligible to run a legal take back program under Indiana law. The term includes:

(1) pharmacies licensed under [IC 25-26](#); and

(2) health care facilities licensed under [IC 16-28](#);

listed as active and in good standing.

(Indiana Board of Pharmacy; [856 IAC 7-2-5](#))

[856 IAC 7-2-6](#) "Return of unused medication" defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 6. "Return of unused medication" refers to medications that are collected under the auspices of an eligible take back program as established under this article. The term does not include the following:

(1) Medication that is returned for credit, resale, and redistribution.

(2) Drugs that are listed in Schedule 1 controlled substances under Indiana law.

(Indiana Board of Pharmacy; [856 IAC 7-2-6](#))

[856 IAC 7-2-7](#) "Take back program" defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 7. "Take back program" refers to a program or service intended to collect unused or unwanted medication from consumers or patients, and established and run under the guidelines and standards as

laid out in this article.

(Indiana Board of Pharmacy; [856 IAC 7-2-7](#))

[856 IAC 7-2-8](#) "Unused or unwanted medication" defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 16-42-19](#)

Sec. 8. "Unused or unwanted medication" could mean all drugs that fall under the definition of drug as defined in [IC 16-42-19](#). Entities that run take back programs may further define or limit what drugs they are capable or willing to accept for destruction purposes. They are not required or mandated to take all drugs in order to maintain eligibility as a take back program.

(Indiana Board of Pharmacy; [856 IAC 7-2-8](#))

[856 IAC 7-2-9](#) "Vendor" defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-13-3](#)

Sec. 9. "Vendor" means a contracted party that is providing services to the entity that is running a take back program established under this article. A vendor can perform any of the services that are part of the program so long as those services are defined in the contract established between that vendor and the entity. The vendor assumes the liabilities and responsibilities as established in the contract and policies and procedures that apply in each relationship.

(Indiana Board of Pharmacy; [856 IAC 7-2-9](#))

Rule 3. Responsibilities of Entities Who Accept Unused or Unwanted Medications

[856 IAC 7-3-1](#) Personnel

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 1. Entities that run a take back program must have licensed personnel that directly manage and have oversight for implementation and the day-to-day activities of the program and services. The individual responsible for managing the program or services must have an active and in good standing license issued by the Indiana professional licensing agency under [IC 25](#).

(Indiana Board of Pharmacy; [856 IAC 7-3-1](#))

[856 IAC 7-3-2](#) Documented policies and procedures

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 2. Entities that run a take back program must have documented policies and procedures that address all the requirements of [IC 25-26-23](#) and this article.

(Indiana Board of Pharmacy; [856 IAC 7-3-2](#))

[856 IAC 7-3-3](#) Management of vendor relationships

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 3. (a) Entities that run a take back program must maintain a documented contract that provides for the roles and responsibilities of each party performing services related to transportation, destruction, and security, and that is available for review by the board. This section does not require that the contract or services be approved by the board, and does not require a contract where the entity is eligible to perform this services independent of a third party vendor.

(b) The ultimate responsibility for management of the vendor relationship falls to the licensed entity that is running the take back program. Any issues of liability, indemnification, or responsibility on the vendor's part should be addressed in the contractual relationship.

(Indiana Board of Pharmacy; [856 IAC 7-3-3](#))

[856 IAC 7-3-4](#) Prohibition on reuse and resale

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-13-25](#); [IC 25-26-23](#)

Sec. 4. Unused or unwanted medications collected by an entity running a take back program shall not be returned to saleable inventory nor made available for subsequent relabeling and redispensing unless otherwise permitted by law (see [IC 25-26-13-25](#)).

(Indiana Board of Pharmacy; [856 IAC 7-3-4](#))

Rule 4. Policy Regarding Record Keeping

[856 IAC 7-4-1](#) Requirement to keep records

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 1. (a) Entities that engage in a take back program shall be required to keep a record of the following:

- (1) Policies and procedures.
- (2) Personnel involved with or who have access to returned medications.
- (3) Dates when medications were collected by the party responsible for destruction.
- (4) Personnel responsible for destruction, transportation, and security.

This information may be maintained in conjunction or as part of the policies and procedures being utilized by the entity running the take back program.

(b) A proper record validation process must include a documented signature and audit trail that includes review or witness, or both, by two (2) separate individuals, both of which are employed by the entity and one (1) of which must be a licensed individual and will ultimately be responsible for ensuring that drug storage devices are properly sealed, secured, and disposed of, either by means provided by the participating pharmacy or the contracted party. The intent of this process is to ensure safeguards against any or all of the following:

- (1) Diversion.
- (2) Misuse.
- (3) Improper disposal.

Additional details on specific policies and procedures are provided in the article concerning access and security.

(c) Model record keeping logs may be obtained from the board. While an entity is not required to use

these forms, the board provides them as guidance for participating entities as models of an acceptable record keeping mechanism.

(Indiana Board of Pharmacy; [856 IAC 7-4-1](#))

[856 IAC 7-4-2](#) Access to records

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 2. Records shall be made available for review to the following:

- (1) The board.
- (2) Board personnel.
- (3) Other entities as may be determined by the board.

(Indiana Board of Pharmacy; [856 IAC 7-4-2](#))

[856 IAC 7-4-3](#) Use of electronic records

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 3. In instances where an entity that runs a take back program is capable of maintaining records in an electronic format, including any logs, receipts, or other records that might be required under this article, those records may be maintained in an electronic format. However, if maintained electronically, those records must be:

- (1) accessible;
- (2) readily retrievable;
- (3) secure (similar to how other pharmacy records are maintained);
- (4) backed up in the event of disaster; and
- (5) available for board inspection upon request.

This section is intended to apply to all aspects of this article.

(Indiana Board of Pharmacy; [856 IAC 7-4-3](#))

[856 IAC 7-4-4](#) Record retention requirements

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 4. Entities that engage in take back programs are required to maintain the relevant records for a period of two (2) years from the date of destruction or delivery/shipment to the party responsible for destruction.

(Indiana Board of Pharmacy; [856 IAC 7-4-4](#))

Rule 5. Destruction Methods

[856 IAC 7-5-1](#) Requirement for destruction

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 1. Drugs collected by a take back program being implemented under this article are required to be destroyed and may not be resold, reused, redistributed, or otherwise interfered with in any way that might

present an opportunity for harm, misuse, or diversion.

(Indiana Board of Pharmacy; [856 IAC 7-5-1](#))

[856 IAC 7-5-2](#) Required time period for destruction

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 2. The frequency of drug destruction can be determined by the entity that runs the take back programs as determined by need and volume, but destruction must occur at least on a quarterly basis to ensure drugs are not stored indefinitely and do not pose a threat to public health and safety.

(Indiana Board of Pharmacy; [856 IAC 7-5-2](#))

[856 IAC 7-5-3](#) Acceptable methods of destruction

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 3. (a) Entities that run take back programs must use a means of destruction that results in incineration of the drugs ensuring that:

- (1) those destroyed drugs do not pose a risk to public health and safety; and
- (2) the drugs or drug remains do not pose an unacceptable level of risk or harm to water systems or landfills.

Entities that run take back programs that utilize their own means to destroy collected drugs must be able to evidence that their incinerator or destruction method is capable of safely destroying drugs and rendering them harmless to the public.

(b) Entities that do not destroy the collected drugs on site or within their own company must have a contract in place with a vendor that will manage the destruction. The contract must include documented policies and procedures that address destruction. Those policies and procedures must at least include a discussion of the transportation, security, and destruction means that would otherwise comply with section 1 of this rule. A system of receipt or logs, or both, that evidence each destruction, the total weight of the drugs destroyed (not quantity or type), and the date it occurred must be included as a part of this contract.

(c) Entities that wish to utilize a different method of destruction not otherwise listed or discussed in this section may petition the board to approve another documented and proven destruction process. The process must include documented policies and procedures that at least address the following issues:

- (1) Public health and safety.
- (2) Diversion.
- (3) Environmental hazards.

(Indiana Board of Pharmacy; [856 IAC 7-5-3](#))

Rule 6. Privacy Protocols and Safeguards

[856 IAC 7-6-1](#) Privacy generally

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 1. (a) An entity that runs a take back program shall be responsible for ensuring that their take back program:

- (1) does not violate the privacy rights of patients and customers; and
- (2) is consistent with what is otherwise required by state and federal law for protecting the privacy rights of patients.

(b) If an entity running a take back program contracts with vendors to assist in accomplishing components of their programs, the entities shall ensure that privacy rights are protected and addressed in their contract with appropriate indemnification and liability provisions to ensure that those privacy rights are protected.

(Indiana Board of Pharmacy; [856 IAC 7-6-1](#))

[856 IAC 7-6-2](#) Privacy protocols and policy

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 2. (a) An entity that runs a take back program shall be responsible for providing documented policies and procedures that outline how they protect patient privacy consistent with state and federal laws. This policy shall be documented and be a part of the larger set of policies and procedures made available for board inspection.

(b) An entity shall:

- (1) provide privacy training to all staff involved with a take back program; and
- (2) have documentation of the training available for board inspection.

(Indiana Board of Pharmacy; [856 IAC 7-6-2](#))

[856 IAC 7-6-3](#) Notice to patients or customers

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 3. An entity that runs a take back program is required to provide a notice to consumers or patients, or both, a copy of their privacy policy and how they protect consumers private health information from being disclosed. The notice and policy should include a statement to how the drugs are collected, the security safeguards, and the method of destruction. This notice may be posted or provided in any one (1) of the following ways:

- (1) Pamphlets or leaflets that describe the policy available to the public upon request.
- (2) A notice posted on the box or device where the drugs are collected.
- (3) A notice posted in the area where take back occurs and is reasonably accessible to view by patients and other consumers.

(Indiana Board of Pharmacy; [856 IAC 7-6-3](#))

Rule 7. Security Standards

[856 IAC 7-7-1](#) Storage device or drug return receptacle

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 1. An acceptable storage device or drug return receptacle will meet the following criteria:

- (1) Does not allow for the removal of contents except by authorized personnel.
- (2) Is secured in a manner that will only allow authorized personnel to remove the contents of the container.
- (3) Utilizes a design that is tamper resistant and will not represent a risk to patient or customer safety.

(Indiana Board of Pharmacy; [856 IAC 7-7-1](#))

[856 IAC 7-7-2](#) Location of storage device or drug return receptacle

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 2. (a) If the storage device is movable, the device or receptacle, or both, must be:

(1) located in the pharmacy department; and

(2) capable of being monitored by whatever security features or personnel that pharmacy department utilizes.

(b) If the storage device is stationary and secure, then the device or receptacle, or both, may be located anywhere in the interior of the building housing the pharmacy, but only personnel included within this article and as provided for in the policies and procedures of the entity running the take back program may have access to that storage device or receptacle.

(Indiana Board of Pharmacy; [856 IAC 7-7-2](#))

[856 IAC 7-7-3](#) Access to contents and secure method of drop off

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 3. (a) It is not required that licensed personnel physically facilitate the placement of the drugs by the patient or customer into the storage device or receptacle. If done by the patient into a secure device, then no other involvement or documentation need occur. If pharmacy staff is involved in assisting with the drop off and collection of drugs, the personnel involved (one (1) of which shall be licensed) will witness and document that the drop off and placement of the drugs into the storage device or receptacle occurred. All that needs to be included in this acknowledgment and documentation is:

(1) the date and time the drop off occurred;

(2) the names of the personnel that facilitated and witnessed the drop off; and

(3) that the drugs were placed into the appropriate storage device and receptacle for destruction.

The board does not intend that this documentation include the name of the patient, the drugs accepted, or any physical count or inventory of the product.

(b) Only personnel designated in the policies and procedures governing the take back program for each individual entity and program shall have access to:

(1) remove the storage device or devices from the receptacle where the drugs are collected; or

(2) transfer the device to the party performing the destruction services (be that party internal or external).

When the device is accessed for removal of the storage device to transport or facilitate the contents for destruction, the process will involve two (2) personnel for witness and acknowledgment purposes, one (1) of which will be a licensed member of the pharmacy staff.

(Indiana Board of Pharmacy; [856 IAC 7-7-3](#))

[856 IAC 7-7-4](#) Requirement for documented policies and procedures

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 4. Any entity that chooses to run a one (1) time or ongoing take back program is required to maintain documented policies and procedures that will address all the requirements of this article.

(Indiana Board of Pharmacy; [856 IAC 7-7-4](#))

[856 IAC 7-7-5](#) Maintenance, monitoring, and emptying

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 5. (a) The drug receptacle into which drugs are placed or returned must be maintained in such a way as to prevent unintended access, diversion, or harm to the personnel, patients, or customers that might use or be in the vicinity of the receptacle.

(b) The storage device and drug receptacle should be monitored in accordance with the security provisions discussed in this article. The level of monitoring should correspond to the location and permanence of the device and should be focused on reasonably preventing diversion, inappropriate access, and harm to patients or customers, or both. In no instance should the receptacle used to facilitate a take back program be:

- (1) located outside the facility; or
- (2) left in an area incapable of being monitored via security cameras or live personnel.

(c) Emptying the device and receptacle shall be done in accordance with the provisions provided in this section and utilize a log or receipt schedule capable of being audited and maintained as a part of the program's record retention requirements.

(d) In the event that the device being used to accept returned medications is full or exceeds capacity, personnel involved in managing the take back program may remove the contents to the extent necessary to secure the returned medications until such time as personnel can arrange for destruction. Whatever contents are removed must be secured in an area separate from merchandise or prescriptions available for sale to customers or patients. Any additional storage area shall also only be accessible to the personnel named in this article and specified in the entity's policies and procedures. Additionally, if an entity maintains additional storage space, this process and space shall be addressed in their policies and procedures (for example, referenced as "Overflow Policy").

(Indiana Board of Pharmacy; [856 IAC 7-7-5](#))

[856 IAC 7-7-6](#) Requirement for notice or signage of acceptable returns

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 6. If an entity engaged in a drug take back program chooses to limit those drugs that are acceptable for return under that program, the limitations shall be clearly and conspicuously placed on or near the drug receptacle in plain view of the patient or customer returning prescription drugs.

(Indiana Board of Pharmacy; [856 IAC 7-7-6](#))

Rule 8. Transportation Standards

[856 IAC 7-8-1](#) Contracted carrier

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-14](#); [IC 25-26-23](#)

Sec. 1. (a) An entity engaged in a drug take back program that utilizes a vendor for any part of the return and disposal process, the entity shall cause the vendor to sign and adhere to a written contract detailing the relationship between the entity and the vendor, including, but not limited to, the duties, processes, and responsibilities of both the entity and the vendor.

(b) It is acceptable for entities (or their vendors) that run take back programs to utilize a common carrier, such as but not limited to, FedEx, the United States Postal Service, and UPS, that are known carriers that have implemented security and privacy protocols and currently are used as part of the wholesale or mail order drug supply chain.

(c) Entities or vendors that run take back programs may also utilize entities licensed and accredited as wholesale distributors or reverse distributors under [IC 25-26-14](#) to the extent those distributors are capable of providing the destruction or transportation services, or both, that satisfy the criteria outlined in this article.

(Indiana Board of Pharmacy; [856 IAC 7-8-1](#))

[856 IAC 7-8-2](#) Minimum standards

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 2. The following minimum standards shall apply to the transportation solutions utilized by entities that run take back programs or the contracted provider they use:

- (1) An appropriate level of security that protects against diversion.
- (2) Insurance and liability coverage similar to that maintained by common carriers or reverse distributors.
- (3) Does not utilize a vehicle or mode of transportation that is primarily used for personal nonbusiness uses.
- (4) The minimum level of driver licensure required by the state to operate a commercial vehicle for business purposes.

(Indiana Board of Pharmacy; [856 IAC 7-8-2](#))

[856 IAC 7-8-3](#) Compliance with state and federal laws and regulations

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 3. Entities that run take back programs shall comply with applicable state and federal laws and regulations that pertain to transport of prescription drugs for destruction to the extent that they are not addressed in this article.

(Indiana Board of Pharmacy; [856 IAC 7-8-3](#))

Rule 9. Liability and Immunity for Entities Operating a Take Back Program

[856 IAC 7-9-1](#) Liability and immunity defined

Authority: [IC 25-26-23-2](#)

Affected: [IC 25-26-23](#)

Sec. 1. Any person or entity that exercises reasonable care in collecting dispensed drugs or devices for disposal under this section shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to the activities.

(Indiana Board of Pharmacy; [856 IAC 7-9-1](#))

[Notice of Public Hearing](#)

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